IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SEASONS HOSPICE & PALLIATIVE CARE OF MARYLAND, LLC,

Plaintiff,

v. Case No. 1:25-CV-02388

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the United States Department of Health & Human Services,

Defendant.

COMPLAINT FOR JUDICIAL REVIEW OF ADMINISTRATIVE DECISION

Plaintiff SEASONS HOSPICE & PALLIATIVE CARE OF MARYLAND, LLC (the "Hospice"), by and through its undersigned counsel, files this Complaint against Defendant ROBERT F. KENNEDY, JR., in his official capacity as the Secretary of the United States Department of Health and Human Services (the "Secretary"). This case is about Defendant's $9.4 million finding against the Hospice, which the Hospice believes is incorrect and unfair. The Hospice therefore seeks judicial review of the decision rendered by the Administrative Law Judge ("ALJ") of the Office of Medicare Hearings and Appeals ("OMHA") in OMHA case number 3-14036175320 and in relation to Medicare Appeals Council ("Council") docket number M-25-1215.

PARTIES

1. The Hospice is a Maryland limited liability company with its principal place of business located at 5457 Twin Knolls Rd, Ste 100, Columbia, Maryland 21045.[1]

[1] The Maryland Secretary of State currently lists 7008 Security Boulevard, Suite 200, Baltimore MD, 21244 as the Hospice's Principal Office. The Hospice is in the process of updating this information. Notwithstanding, venue is still proper in this Court because the Hospice's principal place of business is still located in this judicial district.

2. At all times relevant hereto, the Hospice was a Medicare-certified company offering hospice services in Maryland.

3. Defendant, Robert F. Kennedy, Jr., is the Secretary of the United States Department of Health and Human Services ("HHS") and the proper defendant in this action pursuant to 42 C.F.R. § 405.1136(d)(1).

JURISDICTION AND VENUE

4. This action arises under the United States Constitution, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. ("Medicare Act"), and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*. (the "APA").

5. Prior to filing this Complaint, the Hospice filed appeals and received determinations as to all issues presented below. The Council did not issue a final decision or dismissal order or remand the case to the ALJ within 90 calendar days of receipt of the Hospice's Request for Review. *See* 42 C.F.R. § 405.1100(c). Accordingly, on May 12, 2025, the Hospice properly requested that the appeal be escalated to federal district court as permitted by 42 C.F.R. § 405.1132(a).

6. The Hospice has thus exhausted all administrative appeals and has no administrative remedy available to it. The ALJ's decision is, therefore, the final administrative decision and is appealable to this Court under 42 C.F.R. § 1395ff(b), 42 C.F.R. § 405.1132, and 42 C.F.R. § 405.1136.

7. On May 23, 2025, the Council issued an order granting the Hospice's request for escalation. This Complaint is timely filed within 60 calendar days after the Hospice received the Council's order. *See* 42 C.F.R. § 405.1132(b).

8. Jurisdiction is proper pursuant to 28 U.S.C. § 1331, which vests federal district courts with "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States," and 42 U.S.C. § 1395ff(d), which authorizes judicial review of the ALJ's decision.

9. Venue is proper pursuant to 42 U.S.C. § 1395ff(b) and 42 C.F.R. § 405.1136(b)(1), as the Hospice's principal place of business is located in this judicial district.

10. The amount in controversy exceeds the threshold amount of $1,900.00 for judicial review set forth in 89 Federal Register 79295 (effective Jan. 1, 2025).

LEGAL FRAMEWORK: DUE PROCESS

11. The Fifth and Fourteenth Amendments of the U.S. Constitution guarantee rights to procedural due process. *See* U.S. Const. amend. V; U.S. Const. amend. XIV, § 1.

12. Procedural due process constrains "governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment." *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976).

13. To demonstrate a violation of procedural due process rights, a plaintiff must show "(1) a cognizable liberty or property interest; (2) the deprivation of that interest by some form of state action; and (3) that the procedures employed were constitutionally inadequate." *Davison v. Rose*, 19 F.4th 626, 642 (4th Cir. 2021) (quoting *Shirvinski v. U.S. Coast Guard*, 673 F.3d 308, 314 (4th Cir. 2012)).

14. To have a constitutionally protected property interest in a benefit, a person must clearly have "a legitimate claim of entitlement to it." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972).

15. As this Court has recognized, a health care provider "certainly has a property interest in the ongoing Medicare payments for services rendered to patients." *Anchorage SNF, LLC v. Padilla*, No. 1:22-CV-00166-JRR, 2023 WL 1107994, at *7 (D. Md. Jan. 30, 2023) (citations omitted).

16. To determine whether the procedures at issue were constitutionally adequate, courts consider: (1) the private interest affected, (2) the government's interest, and (3) the risk of erroneous deprivation of the private interest under the procedures used. *Mathews*, 424 U.S. at 335.

17. Hospices are statutorily entitled to be paid for services provided to Medicare beneficiaries that meet Medicare program requirements. *See* 42 U.S.C. § 1395f.

18. The Health Care Financing Administration ("HCFA"), the predecessor to the Centers for Medicare and Medicaid Services ("CMS"), has indicated that when challenging the use of statistical sampling to project overpayments, providers can vindicate their rights to procedural due process only if they have a "full opportunity to demonstrate that the overpayment determination is wrong." Health Care Fin. Admin., Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers, Ruling No. 86-1 (Feb. 20, 1986).

<u>LEGAL FRAMEWORK: THE MEDICARE HOSPICE BENEFIT</u>

19. The Medicare Hospice Benefit is a benefit under Medicare Part A, a 100% federally subsidized health insurance program. It is administered by CMS on behalf of HHS. The Medicare Hospice Benefit pays a predetermined fee, based on the level of care provided by the hospice provider, for each day an eligible individual receives hospice care.

20. Through the Medicare Hospice Benefit, Medicare covers reasonable and necessary hospice services provided to eligible individuals. Services available under the Medicare Hospice Benefit are "comprehensive" and include (a) nursing care and services provided by or under the

supervision of a registered nurse; (b) medical social services provided by a qualified social worker under the direction of a physician; (c) physician services; (d) counseling services, including bereavement, dietary, and spiritual counseling; (e) short-term inpatient care; (f) medical supplies, including drugs and biologicals; (g) home health aide / homemaker services; and (h) physical, respiratory, occupational, and speech therapy services. 42 C.F.R. § 418.202; *see also* 42 C.F.R. § 418.3; 42 U.S.C. § 1395x(dd). The all-inclusive daily rate paid to hospices encompasses a broad set of palliative services, including medical director supervision, development of the patient's plan of care, nursing services, and other medical, social, and spiritual support. Services that are reasonable, necessary non-administrative patient care are separately billable under the Medicare Hospice Benefit. *See* Medicare Benefit Policy Manual, Ch. 9 § 40.1.3.

21. To receive the Medicare Hospice Benefit, an eligible individual must file an election statement acknowledging that they have "been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions." 42 C.F.R. § 418.24. Palliative care is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering[;]…addressing physical, intellectual, emotional, social, and spiritual needs[;] and…facilitat[ing] patient autonomy, access to information, and choice." 42 C.F.R. § 418.3. The election statement must also acknowledge that "certain Medicare services" are waived by the election, namely "Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition," except for services provided by the designated hospice or the individual's attending physician. 42 C.F.R. § 418.24; *see also* 42 U.S.C. § 1395y(a)(1)(c) ("[N]o payment may be made…for any expenses incurred for items or services…in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal

illness."). Hospice patients are free to revoke the election of the Medicare Hospice Benefit at any time and for any reason. 42 C.F.R. § 418.28.

22. Hospices are required to provide patients who elect the Medicare Hospice Benefit everything those patients would normally receive on a fee-for-service basis for palliation of their terminal illnesses and related conditions (*e.g.*, medications, physician visits, durable medical equipment), *including* things Medicare would have otherwise paid for had the patients not elected hospice. *See* 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux) (Congress has confirmed that, absent hospice care, the government is otherwise required to pay for "whatever palliative services are needed to manage [the patient's] terminal illness.").

23. The Medicare Hospice Benefit requires that all hospice care and services furnished to patients and their families must be provided in accordance with an individualized, written plan of care. 42 C.F.R. § 418.56(b), 42 C.F.R. § 418.200. The hospice is required to designate an interdisciplinary group—including, at a minimum, a physician, registered nurse, social worker, and pastoral or other counselor—which, in consultation with the patient's attending physician (if any), is responsible for preparing the plan of care for each patient. 42 C.F.R. § 418.56(a)-(b). The plan of care must be tailored to the specific needs of the patient and family, and must specify the hospice services necessary to meet those needs as they relate to the terminal illness and related conditions. 42 C.F.R. § 418.56(a).

24. The plan of care must include all services necessary for the palliation and management of the patient's terminal illness and related conditions. 42 C.F.R. § 418.56(c). The plan of care must also document the patient's or representative's level of understanding, involvement, and agreement with the plan, in accordance with hospice policy. *Id.*

25. The interdisciplinary group, in collaboration with the patient's attending physician (if any), is required to review, revise, and document the plan of care as frequently as the patient's condition requires, but no less frequently than every 15 calendar days. 42 C.F.R. § 418.56(d). There is no statutory or regulatory requirement that the plan of care be signed by any particular individual(s); the regulations require only that the hospice demonstrate that the plan of care was reviewed at the required intervals. *See id.* Additionally, the regulations do not require a separate plan of care for each level of hospice care (*see* Paragraph 30); rather, the need for each level of care a patient may require must be documented within the existing plan of care. Only one plan of care is required for each patient. *See* 42 C.F.R. § 418.56, 42 C.F.R. § 418.200.

26. The government conditions reimbursement to providers of hospice services on a certification of hospice eligibility. 42 U.S.C. § 1395f. The Medicare Hospice Benefit is organized around benefit periods, *i.e.*, two 90-day benefit periods followed by an unlimited number of 60-day benefit periods. 42 U.S.C. § 1395d(a)(4). The hospice provider must obtain a written certification that the individual is terminally ill (a "CTI") "at the beginning of [each benefit] period" and "before it submits a claim for payment." 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.22. For the initial 90-day benefit period, a hospice provider must obtain a CTI from (1) the hospice's medical director or a physician in the hospice interdisciplinary group (a "Hospice Physician"), and (2) the individual's designated attending physician (the "Designated Attending") (if any). For all subsequent benefit periods, a CTI need only be obtained from a Hospice Physician. 42 U.S.C. § 1395f(a)(7)(A)(ii).

27. Given the nuances and complexities involved in prognostication, as described below, Congress and CMS have entrusted physicians with the responsibility to determine whether a patient's overall condition meets the definition of "terminally ill." 42 U.S.C. § 1395f(a)(7); 70

Fed. Reg. 70532, 70539 (Nov. 22, 2005) ("It is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill."). An individual is "terminally ill" when the Designated Attending (if applicable) and a Hospice Physician exercise their clinical judgment to conclude that "the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course." 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3. A "life expectancy" of 6 months or less means that, in the clinical judgment of the Designated Attending (if applicable) and/or Hospice Physician, the individual's clinical status at the time of certification is more likely than not (*i.e.*, a probability of > 50%) to result in death within six months based on the normal course of the individual's illness. 42 C.F.R. § 418.3.

28. Several changes have been made to the Medicare Hospice Benefit over the years to ensure that Designated Attendings and Hospice Physicians who complete CTIs ("Certifying Physicians") are closely involved in evaluating individuals to predict prognosis and determine eligibility. *See, e.g.*, 75 Fed. Reg. 43236 (July 23, 2010). For example, CTIs must now include a narrative description of the individual ("CTI Narrative") and an attestation "confirm[ing] that [the Certifying Physician] composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient." 42 C.F.R. § 418.22(b)(3)(iii). Additionally, CTIs for all 60-day benefit periods must be preceded by a "face-to-face encounter" ("F2F") in which a Hospice Physician or hospice nurse practitioner visits an individual to gather clinical findings to determine their continued eligibility for hospice care. Certifying Physicians must explain, in the CTI Narrative, why the F2F clinical findings support a life expectancy of six months or less. 42 C.F.R. §§ 418.22(a)(4) and (b)(3)(v).

29. The current Medicare framework does not preclude reimbursement for periods of hospice care that extend beyond six months. There used to be a 210-day statutory limit on hospice

care, but Congress removed that limitation in 1989 in recognition of the uncertainty of prognosis. *See* 42 U.S.C. § 1395d(d)(1) (establishing that hospice providers may collect reimbursement for an unlimited number of benefit periods); *see also* Medicare Catastrophic Coverage Repeal Act of 1989; 70 Fed. Reg. 70532, 70533 (Nov. 22, 2005). In a Program Memorandum to Intermediaries/Carriers, CMS has stated:

> Recognizing that prognoses can be uncertain and may change, Medicare's benefit is not limited in terms of time. Hospice care is available as long as the patient's prognosis meets the law's six-month test. This test is a general one. As the governing statute says: "The certification of terminal illness of an individual who elects hospice shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." CMS recognizes that making medical prognostication of life expectancy is not always an exact science. ***Thus, physicians need not be concerned. There is no risk to a physician about certifying an individual for hospice care that he or she believes to be terminally ill***.

Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article, CMS-Pub. 60AB (Mar. 28, 2003) (quoting 42 U.S.C. § 1395f(a)(7)) (emphasis added). CMS also has made this point clear in its guidance manuals, stating that "[t]he fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits." Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10.

30. Under the Medicare hospice benefit, payment amounts are generally based on one of the following four levels of care:

a. Routine Home Care: The patient receives hospice service while "at home and…not receiving continuous care." 42 C.F.R. § 418.302(b)(1).

b. Continuous Home Care: During "brief periods of crisis," the patient receives hospice care predominantly consisting of nursing care on a continuous basis while at home. 42 C.F.R. § 418.302(b)(2).

c. Inpatient Respite Care: The patient "receives care in an approved facility on a short-term basis for respite" of a personal caregiver. 42 C.F.R. § 418.302(b)(3).

d. General Inpatient Care ("GIP"): The patient receives care "in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings." 42 C.F.R. § 418.302(b)(4).

31. The Medicare program is administered by the Secretary through CMS which, in turn, contracts with private entities to perform certain functions on its behalf. These functions include, but are not limited to, claims processing for reimbursement submitted by Medicare providers and audits of such claims to ensure that they meet the requirements set forth in the Medicare statute and its implementing regulations.

32. Medicare claims are processed by Medicare Administrative Contractors ("MACs"). Other CMS divisions or contractors, such as the CMS Center for Program Integrity ("CPI") and Uniform Program Integrity Contractors ("UPICs"), were and are authorized by CMS to audit claims for payment presented to Medicare by health care providers relating to services they provided to Medicare beneficiaries. These audits were and are performed on a post-payment basis to ensure that the claims complied with Medicare coverage and documentation requirements at the time they were submitted for reimbursement.

33. If an auditor—whether a CMS division or a CMS contractor—audits and denies a claim, the affected provider may avail itself of an administrative appeal process to contest the claim denial(s). This appeals process consists of five stages: (i) redetermination, (ii) reconsideration, (iii) a hearing before an ALJ, (iv) review by the Council, and (v) judicial review by a federal district court.

34. Requests for redetermination are processed by MACs. Requests for reconsideration are handled by separate contractors known as Qualified Independent Contractors ("QICs"). Hearing requests are adjudicated by ALJs in OMHA. Requests for review are processed by the Council, which is a component of the HHS Departmental Appeals Board.

LEGAL FRAMEWORK: STATISTICAL SAMPLING AND EXTRAPOLATION

35. Extrapolation is permissible only "when claims are voluminous…and when a case-by-case review is not administratively feasible." Health Care Fin. Admin., Ruling No. 86-1 (emphasis added).

36. Courts have refused to allow extrapolation when it is not the only method available to establish overpayment—for example, when discrete claims can be analyzed and reviewed to determine whether they were billed in error. *See, e.g.*, *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *7 (D.S.C. June 25, 2015), order corrected, 2015 WL 4128919 (D.S.C. July 6, 2015), and aff'd in part, appeal dismissed in part sub nom. *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017) (citing *United States v. Friedman*, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993)).

37. CMS sets forth instructions on performing statistical sampling and extrapolation in Chapter 8 of the Medicare Program Integrity Manual ("MPIM"), CMS Pub. No. 100-08. The purpose of these instructions is "to ensure that a probability sample drawn from the sampling frame of the target population yields a valid estimate of an overpayment in the target population." MPIM § 8.4.1.1.

38. ALJs are bound by "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs," according to 42 C.F.R. § 405.1063(a). ALJs are not bound by "CMS program

guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a).

39. However, because the MPIM has not been promulgated as a regulation by HHS, it cannot "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" through the Medicare program. 42 U.S.C. § 1395hh(a)(2).

40. Further, the MPIM itself intends auditors to base their statistical sampling and extrapolation methodology on generally accepted statistical principles as well as the MPIM. *See* MPIM § 8.4.1.5 ("The sampling methodology used in estimations of overpayments must be reviewed and approved by a statistician or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically appropriate sample is drawn, and that appropriate methods for estimating the overpayments are followed."). The MPIM also lists minimum criteria for these statisticians, including specified combinations of coursework and years of experience "applying methods of statistical sampling and interpreting the results." *See id.*

41. Statistical sampling involves the selection of a smaller group of claims—a sample—from a larger universe of the same kinds of claims. Auditors must take care in determining how large the sample will be because it has "a direct bearing on the precision of the estimated overpayment." MPIM § 8.4.4.3. Precision reflects the uncertainty in the overpayment estimate, measured as a percentage of the average. Statisticians choose a precision to target, and they input the targeted precision into a formula in order to calculate what sample size is necessary—how many claims the auditor would need to review—to achieve the targeted precision. Precision is represented by a percentage; a higher percentage reflects a *worse* precision. The MPIM

instructs auditors not to choose a sample size arbitrarily but to consider multiple factors, including the precision, to determine the sample size. *See id.*

42. The auditor continues the sampling process by drawing from the data set the universe of claims, which consists of claims the provider submitted during the review period. *See* MPIM § 8.4.3.2.1. The universe must include "all claim lines that meet the selection criteria." MPIM § 8.4.3.2.

43. From the universe, the auditor will next select the sampling frame—a list of "all the possible sampling units from which the sample is selected." MPIM § 8.4.3.2.3. The MPIM directs auditors to remove claims that "have been subject to a prior review" in forming the sampling frame. MPIM § 8.4.3.2.

44. The auditor then uses a sampling process to choose the sample from the sampling frame. *See* MPIM § 8.4.4.1 (stating that the auditor "shall identify the sampling methodology to be followed").

45. After the sample is chosen, each claim in the sample is reviewed to determine whether the claim was paid appropriately, underpaid, or overpaid. *See* MPIM § 8.4.6.3 (requiring auditors to document "[t]he amount of all overpayments and underpayments and how they were determined").

46. If extrapolation is used, these results are then extrapolated across the universe to estimate the total overpayment amount. *See* MPIM § 8.2.1.1 ("A projected overpayment is the numeric overpayment obtained by projecting an overpayment from statistical sampling for overpayment estimation to all similar claims in the universe under review.").

47. However, Section 1893(f)(3) of the Act, codified at 42 U.S.C. § 1395ddd(f)(3), prohibits Medicare auditors from using extrapolation unless HHS has determined there is a

"sustained or high level of payment error" or failure of educational efforts to correct such errors. Accordingly, MPIM § 8.4.1.2 emphasizes that Section 1893(f)(3) "mandates that *before* using extrapolation…to determine overpayment amounts…, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error" (emphasis added).

48. At the time SafeGuard initiated the audit and performed the sampling, the available methods of determining a sustained or high level of payment error included:

- high error rate determinations by the contractor or by other medical reviews (i.e., *greater than or equal to 50 percent from a previous pre- or post-payment review*);
- provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);
- CMS approval provided in connection to a payment suspension;
- information from law enforcement investigations;
- allegations of wrongdoing by current or former employees of a provider/supplier; and/or
- audits or evaluations conducted by the OIG [HHS's Office of Inspector General]. MPIM § 8.4.1.4 (emphasis added).

49. Under Section 1893(f)(3) of the Act and MPIM § 8.4.1.2, the determination of a high level of payment error is not subject to review. However, Section 1893(f)(3)'s prohibition against review violates providers' due process rights. In another recent case, another provider challenged the Defendant's decision to keep using extrapolation even though the error rate dropped to only 9% after most of the claim denials were overturned, closely mirroring this case. *See Merit Leasing Co. v. Becerra*, No. 1:23 CV 859, 2023 WL 8357441 (N.D. Ohio Dec. 1, 2023). The provider argued that the Defendant's use of extrapolation without giving providers a meaningful process to challenge it violates providers' due process rights. *See id.* The court denied HHS's motion to dismiss. *See id*.

50. Even if Section 1893(f)(3) did not violate providers' due process rights, HHS and the courts can review *whether the auditor ever made such a determination* before deciding to extrapolate. Neither Section 1893(f)(3) nor MPIM § 8.4.1.2 prohibits such review.

51. Further, under both generally accepted statistical principles and the MPIM, statistical samplings are invalid if they do not result in a probability sample. *See* MPIM § 8.4.2. A probability sample is one in which each sample, and each unit of each possible sample, has "a known probability of selection." *Id.*

52. Relatedly, auditors must "document all steps taken in the random selection process exactly as done to ensure that the necessary information is available for anyone attempting to replicate the sample selection," MPIM § 8.4.4.2, and "maintain complete documentation of the sampling methodology that was followed," MPIM § 8.4.4.4. This includes documenting the universe definition and elements, period covered, sampling unit definitions and identifiers, dates of service, source, sampling frame, and the random numbers used and how they were selected. MPIM § 8.4.4.4.1. This same section requires that documentation "be kept in sufficient detail so that the sample frame can be re-created should the methodology be challenged." *Id.*

53. The Council has reversed extrapolations because the auditor failed to maintain documentation necessary to replicate the sampling process, emphasizing its importance to providers' due process rights. *See, e.g.*, *Glob. Home Care, Inc.*, M-11-116, at 4 (Medicare Appeals Council Jan. 11, 2011) ("The sampling frame cannot be recreated from the documentation present. Without this basic documentation, a provider does not have the information and data necessary to mount a due process challenge to the statistical validity of the sample, as is its right under CMS Ruling 86-1."); *Podiatric Med. Assocs.*, M-10-230, at 20 (Medicare Appeals Council June 22, 2010) ("It is well-established that due process affords an appellant provider the right to examine

audit results in order to mount a proper challenge in the appeals process….Absent supporting evidence, the appellant is deprived of its ability to review the extrapolation in question.”).

54. The purpose of Medicare program integrity audits is to recover accurate overpayment amounts after accounting for both underpayments and overpayments. *See Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 337 (5th Cir. 2017) (“Congress created the Medicare Integrity Program through which the Secretary contracts with private entities ‘for the purpose of identifying *underpayments and* overpayments and recouping overpayments[.]’”) (citing U.S.C. § 1395ddd(a) and quoting 42 U.S.C. § 1395ddd(h)(1)) (emphases added).

55. When creating the sampling frame, auditors must include potential underpayments. Ruling No. 86-1, the ruling that CMS points to as establishing its authority to extrapolate, shows that extrapolation must account for all potential underpayments in order to arrive at an accurate overpayment estimate. *See* HCFA, Ruling No. 86-1 (“Section 1815(a) of the Social Security Act, 42 U.S.C. 1395g(a), authorizes ‘necessary adjustments on account of previously made overpayments *or underpayments*’ under Medicare Part A.... In addition, section 1861(v)(1)(A)(ii) of the Act, 42 U.S.C. 1395x(v)(1)(A)(ii), provides for the ‘making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the *aggregate* reimbursement produced by the methods of determining costs proves to be either *inadequate or* excessive.’”) (emphases added).

56. Courts have recognized that excluding zero-paid claims from the sampling frame artificially inflates the overpayment estimate. *See, e.g.*, *Cent. Louisiana Home Health Care, L.L.C. v. Price*, No. 1:17-CV-00346, 2018 WL 7888523, at *16 (W.D. La. Dec. 28, 2018) (“The [HHS] interpretation of the MPIM regulations to exclude all unpaid claims clearly results in a

substantially higher overpayment calculation. In this case, that amount was recalculated to about $5,000,000 higher.").

57. Accordingly, many sections of the MPIM require auditors to net underpayments against overpayments when estimating the total overpayment amount. *See*, *e.g.*, MPIM § 8.4.5.2 ("Sampling units that are found to be *underpayments*, in whole or in part, are *recorded as negative overpayments* and *shall be used in calculating the estimated overpayment*.") (emphasis added); MPIM § 8.4.4.4.4 ("Worksheets shall be used in calculating the *net* overpayment. The worksheet shall include data on the claim number, line item, amount paid, audited value, amount overpaid, reason for disallowance, etc., so that each step in the overpayment calculation is clearly shown. *Underpayments identified during reviews shall be similarly documented*.") (emphases added).

STATEMENT OF FACTS

58. In a letter dated May 9, 2023, the UPIC SafeGuard Services, LLC ("SafeGuard"), on behalf of CMS, informed the Hospice of its intention to audit sampled claims related to services provided by the Hospice.

59. On May 22, 2023, SafeGuard requested medical and billing records from the Hospice pertaining to a "random sample" of 69 claims the Hospice had submitted for payment. The Hospice promptly complied with this request and provided SafeGuard with thousands of pages of responsive records for review.

60. In a methodology statement dated October 26, 2023 ("Methodology Statement"), SafeGuard set forth the methodology it used to conduct the statistical sampling. The Methodology Statement stated the universe criteria, including but not limited to the dates of service (January 1, 2020, through March 31, 2023) and paid dates (January 1, 2020, through April 21, 2023). The

Methodology Statement also indicated that it chose the sample of 69 claims (worth a total of \$295,042.70[2]) from a universe of 15,085 claims (worth a total of \$68,551,417.61).

61. In a "Review Results" letter dated October 26, 2023 ("Results Letter"), SafeGuard informed the Hospice that for 41 of the 69 claims reviewed (worth a total of \$175,580.79), the records allegedly did not support: (1) that the plans of care were reviewed as frequently as required, based on the lack of signatures by the physician and other disciplines or the lack of meeting notes; (2) the beneficiaries' terminal prognoses; (3) that the physician and/or nursing visits were billed appropriately; and (4) the beneficiaries' need for GIP services. Based on an extrapolation of the sample results, the MAC, CGS Administrators, LLC ("CGS"), in a November 22, 2023, Request for Overpayment (the "Initial Request for Overpayment"), estimated that the Hospice received \$32,549,440.59 in unallowable Medicare reimbursement for hospice services. The Initial Request for Overpayment demanded that the Hospice refund to Medicare the portion of the estimated overpayment amount attributable to the claims that did not meet Medicare requirements.

62. The Hospice initiated an appeal of the Results Letter and Initial Request for Overpayment through the Medicare administrative appeals process. In a redetermination request dated December 14, 2023, the Hospice refuted the findings set forth in the Results Letter and Initial Request for Overpayment.

63. CGS issued a partially favorable redetermination decision on February 7, 2024. CGS issued partially favorable decisions for 4 claims and unfavorable decisions for the remaining 37 claims.

[2] The Methodology Statement incorrectly indicated that the amount paid for all claims in the sample was \$394,993.78. The correct amount, \$295,042.70, is shown in the Stratified Sample Proportional Optimal Allocation Spreadsheet (ALJ Case File 67), at the bottom of the "PIVOT_02_2024" worksheet.

64. On May 3, 2024, the Hospice filed a request for reconsideration with C2C Innovative Solutions, Inc. ("C2C"), the QIC, appealing all denied claims. The reconsideration request included patient clinical summaries prepared by an expert hospice physician, as well as approximately 200 pages of documents to challenge the technical denials.

65. On May 22, 2024, the Hospice submitted a supplement to the reconsideration request that included a statistical expert report by expert statistician Bo Martin, Ph.D., dated May 21, 2024; Dr. Martin's curriculum vitae; two spreadsheets created by the Hospice that Dr. Martin used to prepare his report; and one spreadsheet created by Dr. Martin and referenced in his report. Also attached to the supplement were election statements for two patients.

66. In its reconsideration decision dated July 12, 2024, C2C issued a partially favorable decision, leaving 26 claims fully or partially denied.

67. On August 5, 2024, the Hospice filed a request for hearing before an ALJ, seeking review of all remaining denied claims. On August 26, 2024, the Hospice received notice that the appeal would be adjudicated by ALJ Gina Shin.

68. In advance of the scheduled ALJ hearing, on September 19, 2024, the Hospice submitted a position statement to ALJ Shin and sent a copy to SafeGuard. The position statement summarized certain relevant legal, medical, and statistical authorities that supported the propriety of the claims at issue and demonstrated the invalidity of SafeGuard's sampling methodology and extrapolation. The position statement included an updated statistical expert report from Dr. Martin. SafeGuard did not submit any position papers before the hearing.

69. The hearing took place before ALJ Shin on September 26, 2024, and was continued on October 4, 2024.

70. At the hearing, the expert hospice physician provided medical expert testimony on behalf of the Hospice, opining that the medical records supported that each patient with a relevant clinical denial was terminally ill and eligible for hospice services consistent with the level of care received. Ms. Rebecca Tinus, Medical Review Manager for SafeGuard, testified on behalf of SafeGuard, which appeared as a participant.

71. Dr. Martin explained how, based on his thorough analysis of the statistical sampling and extrapolation materials received, the sampling and extrapolation were statistically invalid. Dr. Martin described how SafeGuard improperly included 18 claims that another CMS contractor had already reviewed, excluded at least 11 claims from the universe without documenting that it did so, designed the sample improperly and with the sole aim of minimizing its own effort, and removed all claims paid zero dollars from the universe, among other failures. Mr. Roumen Kozarev, SafeGuard's Chief Statistician, testified on behalf of SafeGuard. During the hearing, Mr. Kozarev asked ALJ Shin for an opportunity to submit a position paper.

72. Technical difficulties related to CMS's hearing system occurred during the October 4, 2024, continuation of the hearing, preventing the parties from being able to present closing statements.

73. On October 4, 2024, the Hospice submitted to ALJ Shin a list of the 11 claims that SafeGuard excluded without documenting that it did so, as ALJ Shin requested during the hearing. The Hospice also sent a copy of the list to SafeGuard on the same date.

74. On October 10, 2024, ALJ Shin issued an order permitting SafeGuard to submit a position paper regarding the statistical issues and any written closing statements by November 8, 2024, and permitting the Hospice to submit a response to SafeGuard's position paper and any written closing statements by November 22, 2024. On November 8, 2024, SafeGuard submitted a

position paper regarding the statistical issues. On November 22, 2024, the Hospice submitted its written closing statement, which attached Dr. Martin's response to SafeGuard's position paper.

75. On December 31, 2024, ALJ Shin issued a partially favorable decision (the "Decision") that approved four of the 26 claims. ALJ Shin reversed the denials of all claims denied on clinical grounds. Despite the substantial technical documentation and records submitted by the Hospice, the Decision upheld the denial of a number of claims denied on technical grounds without substantially engaging with, or even acknowledging, the Hospice's arguments. ALJ Shin also upheld the statistical sampling and extrapolation.

76. As a result of the Decision, the precision is now 33.5% (a higher percentage reflects a worse precision). This is worse than the 32.5% precision that was deemed unacceptably poor in a federal court case that found the sampling and extrapolation to be invalid. *See Cent. La. Home Health Care, L.L.C. v. Price*, No. 1:17-CV-00346, 2018 WL 7888523 (W.D. La. Dec. 28, 2018).

77. On February 7, 2025, the Hospice submitted to the Council a Request for Review of Administrative Law Judge Medicare Decision seeking review of ALJ Shin's Decision ("Request for Council Review"). In an exhibit to its Request for Council Review, the Hospice provided additional details and examples demonstrating the errors ALJ Shin made in the Decision. That exhibit is attached hereto as Exhibit A and incorporated herein by reference.

COUNT I: VIOLATION OF THE MEDICARE ACT AND ADMINISTRATIVE PROCEDURE ACT

The ALJ Applied the Incorrect Legal Standards

78. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

79. Under the APA, a court reviewing agency action must set aside agency findings that are "not in accordance with law." 5 U.S.C. 706(2)(A). When reviewing agency action, courts must use their own independent judgment to decide questions of law, with no deference to the

agency. *See Loper Bright Enterprises v. Raimondo*, No. 22-1219, 2024 WL 3208360, at *12 (U.S. June 28, 2024) (citing 5 U.S.C. § 706).

80. The failure to apply the correct legal standards or to provide the Court with a sufficient basis to determine that appropriate legal principles have been followed is grounds for reversal.

81. The ALJ applied incorrect legal standards when she committed errors including, but not limited to, the following:

a. Misapplying the requirements of the patient's election statement stated in 42 C.F.R. § 418.24.

b. Inappropriately expanding the plan of care requirements beyond those included in the regulations. *See* 42 C.F.R. § 418.56, 42 C.F.R. § 418.200.

c. Determining certain physician and/or nurse visits were not payable, contrary to CMS guidance and the Medicare Hospice Benefit.

d. Extrapolating in the absence of a determination of a sustained or high level of payment error or a failure of documented educational intervention to correct the error, in violation of 42 U.S.C. § 1395ddd(f)(3);

e. Excluding zero-paid claims, in violation of 42 U.S.C. 1395g(a), 42 U.S.C. § 1395ddd(h)(1), and 42 U.S.C. 1395x(v)(1)(A)(ii); and

f. Committing other errors as described in Exhibit A.

82. Based on this failure to apply the correct legal standards, the Decision should be reversed.

COUNT II: VIOLATION OF THE MEDICARE ACT AND ADMINISTRATIVE PROCEDURE ACT

The ALJ's Decision Is Not Supported by Substantial Evidence.

83. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

84. The ALJ's Decision must be supported by "substantial evidence," and where reliance is placed on one portion of the record in disregard of over-balancing evidence to the contrary, the Court may reverse the Decision.

85. The unfavorable determinations in the ALJ's Decision were not supported by substantial evidence and were contrary to the overwhelming weight of the evidence, as explained in Exhibit A.

86. The submitted IDG meeting sign-in sheets, visit notes, and other technical documentation show, by a preponderance of the evidence, that the Hospice's medical records and supporting documentation were valid and in compliance with all regulatory requirements.

87. Without a rational basis, the ALJ disregarded the evidence submitted by the Hospice and improperly stated the same boilerplate denial that the Hospice did not furnish "sufficient information," despite failing to engage with any of the Hospice's substantive arguments.

88. The ALJ's approval of the statistical sampling and extrapolation was also unsupported by substantial evidence. Through Dr. Martin's expert reports and testimony, the Hospice provided overwhelming evidence of many fatal problems with the sampling and extrapolation. Mr. Kozarev's testimony failed to properly address the specific errors that Dr. Martin identified.

89. Despite the strength of the Hospice's evidence, the ALJ upheld the sampling and extrapolation. The ALJ stated that SafeGuard performed each of the "major steps" of the statistical

sampling outlined in MPIM § 8.4.1.3. In support of this determination, the ALJ copied and pasted long excerpts from the statistical materials produced by SafeGuard or other contractors, then stated, in a conclusory manner, that the sampling and extrapolation met all requirements. The ALJ provided no analysis regarding most of the specific flaws warranting reversal of the extrapolation that the Hospice identified, as described in the Hospice's filings at the administrative level and Dr. Martin's testimony during the hearing. These and other errors show that the Decision's conclusions regarding the statistical sampling and extrapolation were unsupported by substantial evidence.

90. Because the ALJ's Decision was not supported by substantial evidence, it should be reversed.

COUNT III: VIOLATION OF MEDICARE GUIDANCE

91. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

92. The MPIM intends auditors to base their statistical sampling and extrapolation methodology on generally accepted statistical principles as well as the MPIM.

93. The Defendant failed to follow generally accepted statistical principles and the MPIM in multiple ways, including without limitation, the following:

a. Neither CMS nor any of its contractors made a determination of a sustained or high level of payment error before the audit began, violating MPIM § 8.4.1.2 (as well as Section 1893(f)(3) of the Act). SafeGuard stated that it decided to review the Hospice's claims "based on a proactive data project" and that the two issues the data project identified were potential overuse of GIP and a higher number of patients discharged alive. However, a data project is not a determination of a high level of payment error, and on review, SafeGuard found that both issues were unsubstantiated. Even if HHS did make a determination of a high level of payment

error, the Decision failed to address whether HHS erred in not revisiting that determination, as the audit findings and appeal results clearly showed that there was no such error. The error rate was only 26% after reconsideration and has since fallen to 19.2% as a result of the Decision, well below the 50% threshold of MPIM § 8.4.1.4.

b. SafeGuard failed to document the exclusion of at least 11 claims that met the universe criteria. This violated MPIM § 8.4.3.2, which requires that the universe include "all claim lines that meet the selection criteria." It also violated MPIM § 8.4.1.3, which states that one of the "major steps" of statistical sampling is "Defining the universe (target population)," and MPIM § 8.4.4.4.1, which requires that "[d]ocumentation…be kept in sufficient detail so that the sample frame can be re-created should the methodology be challenged."

c. SafeGuard improperly included in its sampling frame claims that another CMS contractor, Noridian Healthcare Solutions, LLC ("Noridian"), had already reviewed. SafeGuard's failure to remove these claims violated MPIM § 8.4.3.2, which says that "claims/claim lines [that] are discovered to have been subject to a prior review" should not be included in the sampling frame. During the hearing, Mr. Kozarev acknowledged that it is improper to include previously reviewed claims in the sampling frame.

d. SafeGuard designed the sample improperly, and with the sole aim of minimizing its own effort. To give one example, SafeGuard acknowledged that it chose the sample size before identifying a targeted precision, which is statistically improper and contradicts SafeGuard's own Methodology Statement. This violated multiple

MPIM provisions, including one of the "major steps" of statistical sampling as outlined in MPIM § 8.4.1.3: "Performing the appropriate assessment(s) to determine whether the sample size is appropriate for the statistical analyses used."

e. SafeGuard removed all claims paid zero dollars from the universe. Statistically, exclusion of zero-paid claims served only to artificially inflate the overpayment estimate. This also violated the many sections of the MPIM that require auditors to net underpayments against overpayments when estimating the total overpayment amount.

94. Because of the Defendant's multiple, serious violations of generally accepted statistical principles and the MPIM, the Decision should be reversed.

COUNT IV: VIOLATION OF THE SOCIAL SECURITY ACT

The Use of Extrapolation Violated Section 1893(f)(3).

95. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

96. The Defendant's use of extrapolation violated Section 1893(f)(3) of the Act. Neither CMS nor any of its contractors made a determination of a sustained or high level of payment error before the audit began.

97. Even if HHS did make a determination of a high level of payment error, the Decision failed to address whether HHS erred in not revisiting that determination, as the audit findings and appeal results clearly showed that there was no such error. SafeGuard found that both issues raised by its "proactive data project" were unsubstantiated, and the payment error rate was only 26% after reconsideration (and is now only 19.2%).

98. Because the use of extrapolation violated Section 1893(f)(3) of the Act, this Court should declare that the extrapolation was statutorily unauthorized and should enjoin the Defendant from using extrapolation in this case.

COUNT V: VIOLATION OF THE HOSPICE'S DUE PROCESS RIGHTS UNDER THE U.S. CONSTITUTION

The Prohibition Against Review Violates the Hospice's Due Process Rights.

99. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

100. The Hospice has a protected property interest because it is entitled to payments for services that met the federal hospice Conditions of Payment.

101. CMS (through Ruling 86-1) and the Council have acknowledged that statistical sampling and extrapolation implicate providers' due process rights, and this Court has acknowledged that providers have a property interest in Medicare payments for services provided to patients.

102. The prohibition against administrative and judicial review of HHS's determination that there has been a sustained or high level of payment error, as set forth in Section 1893(f)(3) of the Act and MPIM § 8.4.1.2, deprives the Hospice of an appropriate level of process. Extrapolation vastly multiplies overpayment estimates—as well as any unresolved errors the auditor has made. Thus, the Hospice faces a tremendous risk that it will be erroneously deprived of funds to which it is entitled if the sole determination that authorizes the extrapolation is unreviewable.

103. Therefore, this statutory and agency prohibition against review violates the Hospice's due process rights under the U.S. Constitution.

104. Because the prohibition against review violates providers' due process rights, this Court should declare that the prohibition against review of the Defendant's determination of a high level of payment error, which is set forth in Section 1893(f)(3) and MPIM § 8.4.1.2, violates the

due process clauses of the Fifth and Fourteenth Amendments of the U.S. Constitution. Moreover, this Court should enjoin the Defendant from using extrapolation in this case.

COUNT VI: VIOLATION OF THE HOSPICE'S DUE PROCESS RIGHTS UNDER THE U.S. CONSTITUTION

The Decision to Use Extrapolation Violated the Hospice's Due Process Rights.

105. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

106. The Defendant's decision to use extrapolation violated the Hospice's due process rights because the Defendant decided to use extrapolation *before* making a determination of a sustained or high level of payment error and failed to revisit that determination once it became clear that there was no such error. This decision deprived the Hospice of an appropriate level of process because it permitted the Defendant to decide to extrapolate for any reason or for no reason at all. Thus, the Hospice is highly likely to be erroneously deprived of funds to which it was entitled.

107. Because the Defendant decided to extrapolate before making a determination of a sustained or high level of payment error and failed to revisit that determination once it became clear that there was no such error, this Court should declare that the Defendant violated the Hospice's due process rights and should enjoin the Defendant from using extrapolation in this case.

COUNT VII: VIOLATION OF THE HOSPICE'S DUE PROCESS RIGHTS UNDER THE U.S. CONSTITUTION

The Exclusion of Claims Paid Zero Dollars Violated the Hospice's Due Process Rights.

108. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

109. The Defendant's exclusion of all claims paid zero dollars violated the Hospice's due process rights. Excluding such claims serves no purpose other than to artificially inflate the

overpayment estimate. The exclusion of these claims placed the Hospice at tremendous risk of being erroneously deprived of funds to which it was entitled.

110. Because the Defendant wrongfully excluded claims paid zero dollars, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the ALJ's Decision that the sampling and extrapolation were valid.

COUNT VIII: VIOLATION OF THE HOSPICE'S DUE PROCESS RIGHTS UNDER THE U.S. CONSTITUTION

The Multiple Fatal Statistical Errors Violated the Hospice's Due Process Rights.

111. The Hospice hereby incorporates by reference paragraphs 1 through 77 herein.

112. The Defendant's failure to adhere to generally accepted statistical principles and its significant departures from its own guidance, the MPIM, violated the Hospice's due process rights.

113. The Defendant decided to extrapolate before determining that there was a high level of payment error, excluded at least 11 claims from the universe without documenting that it did so, improperly included 18 previously reviewed claims in the sampling frame, designed the sample improperly and with the sole aim of minimizing its own effort, and continued to extrapolate even once it became clear that the results of its data project were wrong and there was no high level of payment error. Under any one of these circumstances, the Hospice's risk of being erroneously deprived of funds to which it was entitled was terribly high.

114. As a result of the Defendant's many fatal failures to adhere to generally accepted statistical principles and the MPIM, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the ALJ's Decision that the sampling and extrapolation were valid.

REQUEST FOR RELIEF

WHEREFORE, the Hospice respectfully requests that this Court:

1. Find the ALJ's Decision applied the wrong legal standards;

2. Find the ALJ's Decision was not supported by substantial evidence;

3. Reverse the ALJ's Decision that the supplied documentation did not meet Medicare coverage guidelines for hospice services;

4. Reverse the ALJ's Decision that the sampling and extrapolation were valid;

5. Declare that extrapolation was statutorily unauthorized in this case;

6. Enjoin the Defendant from using extrapolation in this case;

7. Order the Defendant to exclude amounts otherwise payable under Medicare Part B or D from the demand and, in the event this Court determines that extrapolation is permissible, from the extrapolation recalculation;

8. Declare that Section 1893(f)(3)'s prohibition against review of the Defendant's determination of a high level of payment error violates the due process clauses of the Fifth and Fourteenth Amendments of the U.S. Constitution;

9. Declare that the Defendant violated the Hospice's due process rights under the U.S. Constitution;

10. Hold that the Hospice is entitled to reimbursement, with interest, for the claims submitted relating to Medicare that form the basis of this Complaint; and

11. Vacate and Remand the Secretary's final decision for reimbursement of Hospice by the Secretary for the amounts previously recouped from Hospice for the claims submitted relating to Medicare that form the basis of this Complaint with applicable interest;

12. Grant the Hospice any other legal or equitable relief that the Court may deem just and proper.

Dated: July 22, 2025

Respectfully submitted,

HUSCH BLACKWELL LLP

By: *__/s/ Emily Loftis____________*

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